

REMARKS

By this amendment, claims 1 and 17 are revised and claims 2, 3, and 5 are canceled to place this application in condition for allowance. Currently, claims 1, 4, and 6-17 are before the Examiner for consideration on their merits.

In review, claim 1 is revised to include the limitations of claims 2, 3, and 5 as well as the description found in paragraph 2 of the specification and the drawings. With these changes, claim 1 now defines the surgical drape that has a first fenestration that is closed by an incise film and at least one other fenestration that is closed by a cover means. Claim 17 is revised to be consistent with the change made to claim 1.

The cover means is also further defined in that it is firmly bound along the entire perimeter of the second fenestration, is at least in the area of the coverage of the means of reference transparent for radiation emitted by a measurement system, and has a form that is elongated with a closed end on the side facing away from the drape.

Turning now to the prior art rejection, Applicants submit that none of the prior art teaches or suggests all of the features of claim 1, as amended, and a *prima facie* case of anticipation cannot be said to exist.

Since claims 2, 3, 5, and 17 are essentially incorporated into claim 1, a number of the rejections are no longer valid. Consequently, the rejections made and now deemed appropriate are discussed below under the headings of the applied prior art.

United States Patent No. 5,143,091 to Patnode

Patnode discloses a surgical drape with a first and second aperture. Elastomeric pieces covering the apertures are provided with the first fenestration and second fenestration adapted to receive the limb of a patient.

Patnode is not used to reject claims 2, 3, 5, and 17 so that this reference cannot anticipate claim 1, as amended. More particularly, Patnode does not disclose the claimed incise film. Patnode also fails to teach the means of cover for a means for reference protruding from the level of the drape's surface and, more specifically, its features with respect to the binding to the second fenestration, the transparent aspect, and the elongated aspect, all of which are now in claim 1.

United States Patent No. 5,490,524 to Williams

The Examiner cites Williams to reject claims 2 and 3 in combination with Patnode. Williams provides a surgical drape that is adapted to cover either end of a C-arm x-ray machine having a laser targeting device mounted thereon. The surgical drape is made of an x-ray transparent material, such as plastic, and includes a transparent window made of a material that does not diffuse or diffract a laser beam, such as an acetate film.

Regardless of the teachings of Williams, this patent does not teach an incise cover and means of cover for a means of reference that protrudes from the level of the drape's surface. In addition, claim 1 now requires that the cover means be firmly bound with the drape along the entire perimeter of the second fenestration, is transparent to radiation emitted by a measurement system, and is elongated with a closed end on the side facing away from the drape. None of these features are taught or suggested by Williams. Therefore, even if Williams were combined with Patnode, a *prima facie* case of

obviousness is still not present since the claim 1 limitations are still not taught or suggested.

Applicants also submit that the Examiner lacks the necessary reason to take the teachings of Williams and apply them to Patnode. Williams is intended for use on an x-ray machine. Why would one of skill in the art incorporate features of Williams with the drape of Patnode, designed to be used on a patient's foot. There is no reason to look to Williams to modify Patnode and a rejection of this nature could not be sustained on appeal. The Examiner is merely identifying a feature that happens to be known in the art, but is not providing the necessary reason why such a feature can be incorporated into Patnode.

Even after the United States Supreme Court's decision in the case of *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), the following legal principles are still valid, having been endorsed by the Supreme Court or having been unaffected by its decision: (1) the USPTO still has the burden of proof on the issue of obviousness; (2) the USPTO must base its decision upon evidence, and it must **support its decision with articulated reasoning** (slip op. at 14); (3) **merely demonstrating that all elements of the claimed invention exist in the prior art is not sufficient to support a determination of obviousness** (slip op. at 14-15); (4) **hindsight has no place in an obviousness analysis** (slip op. at 17); and (5) Applicant is entitled to a careful, thorough, professional examination of the claims (slip op. at 7, 23, in which the Supreme Court remarked that a poor examination reflected poorly upon the USPTO).

The Examiner is violating the Supreme Court's point (3) above and this means that the rejection based on Williams is not valid and should be withdrawn.

United States Patent No. 7,316,233 to Auerbach

The Examiner addresses the claim 5 limitation by combining Patnode and Auerbach. Auerbach discloses an integrated drape for use in surgical procedures involving anatomical extremities and having a unitary assembled structure. The drape comprises a flexible panel sheet portion having first and second opposing sides and having a fenestration located therethrough. The drape further comprises a flexible elongate sleeve portion having an open proximal end and a closed distal end. The proximal end is integrally attached to the panel sheet and circumscribes the fenestration.

While Auerbach discloses an elongated cover means with a closed end on the side facing away from the drape, Auerbach does not teach a first fenestration with an incise film and no cover means that is transparent for radiation emitted by a measurement system. Therefore, even if the cover means of Auerbach were incorporated with the drape of Patnode, the features of claim 1, as amended, would still not be present and a *prima facie* case of obviousness cannot be said to exist.

United States Patent No. 4,027,665 to Scrivens

The Examiner cites Scrivens to address claim 17 and combines it with Patnode to allege that the use of an incise film on the fenestration of Patnode is obvious. Scrivens discloses a surgical drape particularly suitable for cardiovascular surgery that comprises a main sheet, preferably a T-shaped configuration of flexible drapable material, and at least two fenestrations covered by closure members, which carry a pressure sensitive adhesive

on their lower surfaces. The drape also includes improved means for securing thin, flexible elements such as suction tubing and electrical wires to the upper surface of the drape.

Scrivens does not disclose a cover means which has the claimed features, i.e., is firmly bound along the entire perimeter of the second fenestration, is transparent for radiation emission by the measurement system, and is elongated with its closed end on the side facing away from the drape. Therefore, even if Scrivens were combined with Patnode, the features of claim 1 would still not be taught and a *prima facie* case of obviousness would not exist.

Secondary References to United States Patent No. 5,312,385 to Greco, United States Patent No. 6,697,664 to Kienzle, United States Published Patent Application No. 2002/0069882 to Sklar, United States Patent No. 6,820,622 to Teves, United States Patent No. 5,417,225 to Rubenstein, and United States Patent No. 4,869,271 to Idris

The Examiner has also cited a number of other references to address the limitations in claims 6 and 8 (Greco), claim 9 (Kienzle), claim 10 (Sklar), claim 12 (Teves), and claim 13 (Rubenstein).

None of these secondary references make up for the failings in Patnode, Williams, Auerbach, and Scrivens when addressing the patentability of claim 1, as amended.

Greco provides an apparatus and a method for performing protected pulse irrigation. An impervious collapsible enclosure is provided to encompass that portion of the body upon which the area to undergo pulse irrigation is located. To ensure that no contaminated irrigation fluids come in contact with the operating room staff, the collapsible

enclosure is provided with a means for forming a substantially water-tight seal at each open end of the enclosure.

Kienzle discloses an image guided surgery system to enable a surgeon to move a surgical tool into a desired position relative to a body part. A sterile transparent drape allows a C-arm of the system to be used in a sterile environment, and that includes a portion similar in size and shape to the housing that contains the C-arm localizing emitters, such that the drape fits flush against the localizing emitters, so that their positions may be accurately determined by a localizing device, see paragraph [0027] thereof.

Sklar describes an operating room drape for allowing the presence of a monitor or display panel close to a surgical field while maintaining a sterile field between the monitor and the surgical site. A window in the drape, or the entire drape, is formed of a high clarity material and at least the window is adapted to lie against the monitor screen to provide enhance visibility.

Teves provides a surgical drape as well. A flexible sheet of plastic overlies a flexible substrate and is connected to the substrate at its periphery to create a hollow space into which warm air is pumped. A plurality of tie-downs maintains a low profile for the inflated cover. Removable panels grant access to areas of the body for surgical procedures.

Rubenstein provides a radiation shield including an aperture connected to an edge of the shield by a slit, which is held closed by a reasonable flap. Instrumentation can be inserted through the aperture to contact a patient over whom the shield is draped. By releasing the flap and thereby opening the aperture toward the edge of the shield, the

shield can be removed from the patient without removing the instrumentation inserted through the aperture.

Irdis provides a fenestrated surgical drape which has a fluid collection pouch that is pivotally attached about the fenestration so that the pouch may be selectively attached to either side of the fenestration.

None of the secondary references listed above makes up for the collective failings of Patnode, Williams, Auerbach, and Scrivens in teaching or suggesting each and every feature of claim 1, as amended. Therefore, even if these references were used with Patnode, a *prima facie* case of obviousness would not exist.

PATNODE, AUERBACH, AND SCRIVENS

The Examiner may allege that it would be obvious to combine each of these references to produce a drape having the claimed features such as the incise film over the first fenestration and the cover means. Even using the incise film of Scrivens and the elongated cover means of Auerbach, the combination still fails to teach the transparent feature of the cover means and a *prima facie* case of obviousness would still not exist.

PATNODE, WILLIAMS, AUERBACH, AND SCRIVENS

The Examiner may also allege that claim 1 can be properly rejected based on the combination of all four of the references listed in the heading directly above. However, such a rejection can only be based on hindsight knowing the Applicant's invention. As argued above, the mere identification of the features of an invention in the prior art

does not mean that the invention is obvious. The Examiner must still have to have reasons to combine the prior art in a way so as to arrive at the invention. Applicant submits that the necessary reasoning does not exist to combine four prior art references, all having different aims, in order to formulate a rejection under 35 U.S.C. § 103(a). The Examiner is merely taking select teachings of the prior art for the purpose of making a rejection, not based on what one of skill in the art would find obvious to do.

To recap, the revision to claim 1 means that a *prima facie* case of anticipation no longer exists based on Patnode. In addition, a *prima facie* case of obviousness does not exist against claim 1 since the necessary reasoning does not exist to piece together the prior art so as to arrive at the invention.

Since claim 1 is patentable over the prior art, its dependent claims are also in condition for allowance.

Accordingly, the Examiner is requested to examine this application and pass claims 1, 4, and 6-17 onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

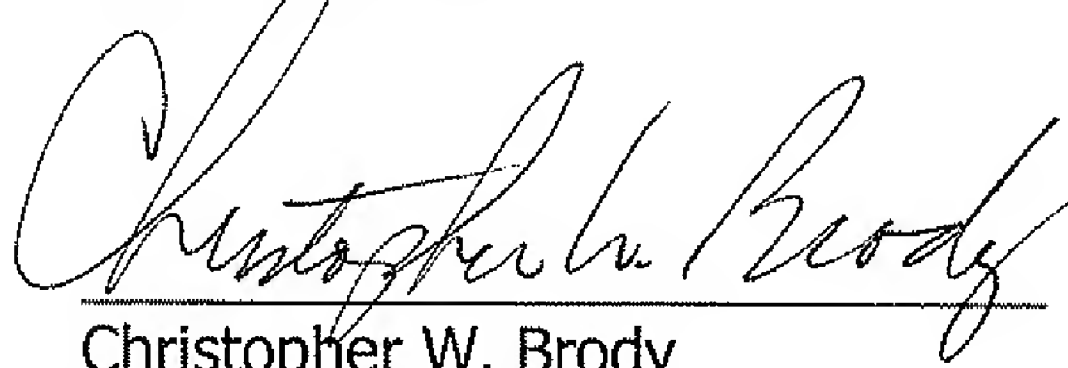
The above constitutes a complete response to all issues raised in the Office Action dated July 21, 2009.

Again, reconsideration and allowance of this application is respectfully requested.

A petition for a three month extension of time is made. Please charge Deposit Account No. 50-1088 the \$555.00 for the three month extension of time.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,
CLARK & BRODY

A handwritten signature in cursive script, reading "Christopher W. Brody", written over a horizontal line.

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